# CVS ANTIBACTERIAL PLUS URINARY PAIN RELIEF- methenamine, sodium salicylate tablet CVS Pharmacy, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### **Drug Facts**

#### Active Ingredients (in each tablet):

Methenamine 162 mg

Sodium Salicylate 162.5 mg (NSAID Nonsteroidal Anti-Inflammatory Drug)

#### **Purpose**

Antibacterial

Analgesic (pain reliever)

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Uses** Temporarily relieves: pain & burning • frequency and urgency of urination

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. If changes in behaviour with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Stomach bleeding warning:** This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you:

- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen or others)
- have 3 or more alcoholic drinks every day while using this product
- have stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older take more or for a longer time than directed

#### Do not use:

- if you are on a sodium restricted diet
- if you are allergic to salicylates (including aspirin) unless directed by a doctor
- if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems unless directed by a doctor

#### Ask a doctor before use if you have

- frequent, burning urination for the first time the stomach bleeding warning applying to you
- history of stomach problems, such as heartburn
- high blood pressure heart disease liver cirrhosis bleeding problems

• diuretic use • ulcers • kidney disease • reached age 60 or older

#### Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant), steroid, diabetes, gout or arthritis drug

When using this product • do not take more than the recommended dosage

#### Stop and ask a doctor if

- product has been used for 3 days
- you experience any of the following signs of stomach bleeding:
- feel faint, vomit blood have bloody or black stools have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs

#### If pregnant or breast feeding, ask a health professional before use.

**Directions:** Adults and children 12 years and over: take 2 tablets with a full glass of water 3 times a day. Drink plenty of fluids. Children under 12 years: ask a doctor

### **Inactive ingredients:**

benzoic acid, croscarmellose sodium, fd&c red #40, fd&c yellow #6, hypromellose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, silicon dioxide, stearic acid, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Other Information:** • each tablet contains 25 mg of sodium • store at 59-86°F (15-30°C) in a dry place • protect from light • Tamper evident: tablets sealed in blisters. Do not use if blister foil or seal is open or damaged.

- HELPS CONTROL THE INFECTION\*
- PLUS GENERAL PAIN RELIEVER

#### **Antibacterial Urinary Pain Relief**

Methenamine and Sodium Salicylate (NSAID)

#### **Packaging**



#### CVS ANTIBACTERIAL PLUS URINARY PAIN RELIEF

methenamine, sodium salicylate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-314
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
METHENAMINE (UNII: J50 O IX95QV) (METHENAMINE - UNII: J50 O IX95QV)	METHENAMINE	162 mg		
SODIUM SALICYLATE (UNII: WIQ 1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SODIUM SALICYLATE	162.5 mg		

Inactive Ingredients		
Ingredient Name	Strength	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

HYPROMELLOSES (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6 I30)

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6 IU)

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

STEARIC ACID (UNII: 4ELV7Z65AP)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

TRIACETIN (UNII: XHX3C3X673)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	PH0 6 1
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:69842-314-24	1 in 1 CARTON	02/22/2017	
1	24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/22/2017	

# Labeler - CVS Pharmacy, Inc (062312574)

# **Registrant** - Reese Pharmaceutical Co (004172052)

# Establishment Name Address ID/FEI Business Operations Reese Pharmaceutical Co 004172052 repack(69842-314), relabel(69842-314)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(69842-314)

Revised: 1/2019 CVS Pharmacy, Inc